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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,395	06/24/2005	David Chow	285-237 PCT US	9017

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MINNEAPOLIS, MN 55402-1498

EXAMINER

WOODALL, NICHOLAS W

ART UNIT	PAPER NUMBER
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3733

MAIL DATE	DELIVERY MODE
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10/29/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/500,395

Applicant(s)

CHOW ET AL.

Examiner

Nicholas Woodall

Art Unit

3733

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 August 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,22,23,36 and 40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,22,23,36 and 40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 June 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>08/06/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This action is in response to applicant's amendment received on 08/15/2007.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

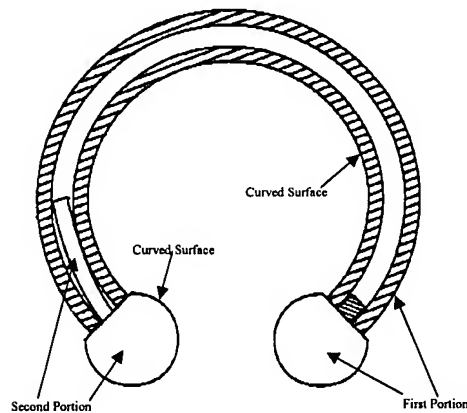
3. Claims 1, 22, and 23 are rejected under 35 U.S.C. 102(e) as being anticipated by Siekierski (U.S. 6,470,709).

Regarding claim 1, Siekierski discloses a device comprising a first portion capable of extending through multiple bone fragments and a second portion capable of being displaced relative to the first portion and capable of being detachably coupled therewith in a locked position to secure multiple bone fragments (see Figure 1 below). Siekierski discloses a device wherein the first portion includes a curved cylindrical body. The examiner is interpreting the cylindrical body of the first portion having a curved surface, which the examiner believes read on the limitations of claim 1. Siekierski discloses a device wherein the second portion includes a curved cylindrical body, wherein the cylindrical body is slidingly disposed within and extending through the cylindrical body of the first portion. The examiner is interpreting the cylindrical body of

Art Unit: 3733

the second portion having a curved surface, which the examiner believes read on the limitations of claim 1. Regarding claim 22, Siekierski discloses a device wherein a distal end of the second portion being enlarged to abut a distal end of the cylindrical body of the first portion. Regarding claim 23, Siekierski discloses a device wherein the proximal end of the cylindrical body of the first portion has an enlarged head capable of abutting an outer surface of bone fragments and wherein the distal end of the first body is capable of being forced outwards to abut an outer surface of another bone fragment in response to a tensile force applied to a proximal end of the second portion.

Figure 1



4. Claims 1, 22, 23, and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by McKinney (U.S. Patent 5,167,665).

Regarding claim 1, McKinney discloses a device comprising a first portion (19) capable of extending through multiple bone fragments and a second portion (23 and 39) capable of being displaced relative to the first portion and capable of being detachably coupled therewith in a locked position to secure bone fragments. McKinney discloses a device wherein the first portion includes a curved cylindrical body. The examiner is interpreting the first portion of the device includes a curved surface (33), which the

examiner believes read on the limitations of claim 1. The examiner notes that reference number 33 designates the head of the body of the device, but the examiner is using the reference number to direct the applicant to the area of the first portion having the curved surface. McKinney discloses a device wherein the second portion of the device includes a curved cylindrical body, wherein the cylindrical body of the second body is slidingly disposed within and extending through the cylindrical body of the first portion. The examiner is interpreting the second portion of the device includes a curved surface (39), which the examiner believes read on the limitations of claim 1. The examiner notes that reference number 39 designates the bead of the mandrel of the device, but the examiner is using the reference number to direct the applicant to the area of the second portion having the curved surface. Regarding claim 22, McKinney discloses a device wherein the distal end of the second portion is enlarged to abut a distal end of the cylindrical body of the first portion. Regarding claim 23, McKinney discloses a device wherein a proximal end of the cylindrical body of the first portion has an enlarged head abutting an outer surface of a bone fragment in the locked position, wherein the distal end of the first body is capable of being forced outwards to abut an outer surface of another bone fragment in response to a tensile force applied to a proximal end of the second portion. Regarding claim 36, McKinney discloses a device inherently capable of being used by a method comprising the steps of displacing a first portion of the device through one of the bone fragments, displacing a second portion of the device through and within the first portion such that an enlarged distal end of the second portion abuts a distal end of the first portion so as to engage the first and second portions of the

device, and displacing the first and second engaged portions relative to one another to a locked position, wherein the bone fragments are secured by the locked in fastener, wherein each of the first and second portions have a curved cylindrical body and wherein the cylindrical body of the second portion is slidingly disposed within and extending through the cylindrical body of the first portion.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claim 40 is rejected under 35 U.S.C. 103(a) as being unpatentable over Vagley (U.S. Patent 6,158,437) and Hochschuler et al. (U.S. Patent 6,099,527); Benderev et al. (U.S. Patent 6,200,633); Lalonde (U.S. Patent 6,315,780); and Brinson (U.S. 5,797,919) are cited as evidence.

Regarding claim 40, Vagley discloses a method of performing a surgical procedure wherein an instrument support tray is provided having a plurality of surgical instruments positioned thereon (column 1 lines 65-67). Vagley further discloses that the tray can be customized to cater to the preferences of a specific surgeon during a specific procedure and in such case may also provide additional equipment preferences of the surgeon. All this is directed toward enhanced efficiency in the surgical site and more accurate and prompt delivery of the correct instrument to the surgeon (column 5 lines 40-50). Vagley defines a surgical procedure as "a procedure performed on a

Art Unit: 3733

patient by a physician, dentist, veterinarian, or other legally authorized health care professional in which the procedure involves a plurality of hand-held instruments and is at least partially invasive" (see column 3 lines 5-10). Hochschuler et al disclose that the kits or trays can include a two-piece bone fastener wherein the two pieces are locked together. Brinson discloses a tray or kit can include a bone clamp wherein a pair of jaws are pivotal relative to each other and can be locked using a locking mechanism. Benderev et al disclose a tray or kit can include a bone fastener manufactured from a shape memory material wherein at least one end has deformable webs that separate and engage an inner surface of the bone. Lalonde discloses a bone clamp wherein a pair of jaws are linearly displaceable relative to one another and can be locked using a locking mechanism. Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to place specific tools, such as fasteners and bone clamps, needed in a tray to cater to the preference of the surgeon during a specific procedure.

Response to Arguments

Applicant's arguments filed 08/15/2007 have been fully considered but they are not persuasive. The applicant's argument that Siekierski does not disclose a bone fastener is not persuasive, it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987). The applicant's argument that Brinson does not teach a bone fastener is not persuasive, it has been held that a recitation with

respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. The device of Brinson is capable of being used to fasten segments of bone together during a surgical procedure if one so desired. Furthermore, the device of Brinson discloses a device comprising a pair of jaws pivotally connected in the proximal end of the device. The phrase "proximal end" does not limit the pivotal connection to be at the extremities of the jaws. A broad definition of end is, "a part or place at or adjacent to an extremity" (www.dictionary.com). Therefore, the pivotal connection only needs to be adjacent the proximal extremities, which Brinson discloses. The applicant's argument that Benderev does not disclose a device made from memory shape alloy, wherein the deformable fingers engage a facet of at least one bone segment in response to heat applied to the device is not persuasive. First, Benderev discloses in column 13 lines 12-15 that the device may be made from plastic deformable or shape-memory materials. Second, the claim states, "...to engage a facet of at least one of the bone segments in response to heat applied to the device...", which is a functional limitation and the device only needs to be capable of performing the function. The device of Benderev is capable of engaging a facet of at least one bone segment in response to heat applied to the device, since the examiner believes it is well known in the art that memory-shape alloys can be actuated by the application of heat. Regarding the applicant's argument that the references of Vagley, Hochschuler, Benderev, Lalonde, and Brinson can not be combined is not persuasive. The reference of Vagley teaches performing a medical procedure wherein an instrument support tray

Art Unit: 3733

is provided having a plurality of surgical instruments positioned thereon. Vagley further discloses the tray can be customized to cater to the preferences of a specific surgeon during specific procedures and also includes providing any additional equipment preferences of the surgeon. These teachings are directed towards enhanced efficiency in the surgical site and more accurate and prompt delivery of the correct instruments to the surgeon. Vagley further defines a surgical procedure as is discussed in the previous office action. The examiner believes that Vagley's teachings of providing a tray having all the necessary instruments and devices for a procedure is combinable with the teachings of the specific devices of the other instruments. The examiner believes it would be obvious to prepare and place specific tools and devices, such as bone fasteners and bone clamps of the separate references, on a tray as taught by Vagley to have any fastener the surgeon may require to increase the efficiency of the procedure.

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO-892 for cited references the examiner felt were relevant to the application.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within

Art Unit: 3733

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nicholas Woodall whose telephone number is 571-272-5204. The examiner can normally be reached on Monday to Friday 8:00 to 5:30 EST..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

nww


EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER